Adrenal gland scanning using PET/CT with a specific tracer (11C-metomidate) in patients with hypertension due to overproduction of aldosterone.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28757

Bron
Nationaal Trial Register

Aandoening

hypertension
primary aldosteronism
adrenal venous sampling

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Hanzeplein 1
9700 RB Groningen
The Netherlands
Overige ondersteuning: University Medical Center Groningen
Hanzeplein 1
9700 RB Groningen
The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Degree of concordance between results of 11C-metomidate PET/CT and those of AVS with respect to differentiation between BAH and APA.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Primary aldosteronism (PA) is a relatively common secondary cause of hypertension. PA is usually due to either bilateral adrenal hyperplasia (BAH) or an aldosterone producing adrenal adenoma (APA). Less frequently, PA is caused by primary unilateral adrenal hyperplasia (PAH). Clinically, PAH behaves like APA and the distinction between these two subtypes can only be made by pathologic examination of the removed adrenal gland, demonstrating either hyperplasia or adenoma, respectively. The recommended treatment for BAH is medical treatment with antihypertensive drugs (aldosterone antagonist), whereas APA and PAH can be cured in many cases by unilateral adrenalectomy. Thus, it is of clinical importance to differentiate correctly between BAH and APA/PAH. Current guidelines recommend adrenal venous sampling (AVS) as the gold standard for the differentiation between BAH and APA/PAH in every patient with PA who is a candidate for surgery. However, AVS is an invasive diagnostic test and is therefore not without risks. Moreover, AVS requires an experienced radiologist, and is time-consuming and expensive. Therefore, there is an urgent need for a non-invasive, faster and less expensive diagnostic test which can correctly distinguish between the two main subtypes of PA. PET/CT with 11C-metomidate has successfully been used as a functional imaging technique for several adrenal gland diseases. Until now, its value in the differential diagnosis in PA has not been well investigated. Our hypothesis is that 11C-metomidate PET/CT is selectively taken up by aldosterone producing adrenal cortical tissue, resulting in a symmetrical tracer uptake in case of BAH and in a unilateral tracer uptake in a patient with an APA or PAH.

Objective:

Main objective is to determine whether 11C-metomidate PET/CT can differentiate between BAH and APA/PAH.

Study design:

Comparative diagnostic study.

Study population:

Adult patients (=/> 18yrs) with PA after a successful AVS (n=10).

Intervention:

Patients will undergo a whole-body 11C-metomidate PET/CT scan.

Main study parameters/endpoints:

Main study parameter is the concordance between the results of AVS (=gold standard) and 11C-metomidate PET/CT.

Doel van het onderzoek

Our hypothesis is that 11C-metomidate is selectively taken up by aldosterone producing adrenal cortical tissue, resulting in a symmetrical tracer uptake in case of bilateral adrenal hyperplasia (BAH) and in a unilateral tracer uptake in a patient with an aldosterone producing adenoma (APA)or primary adrenal hyperplasia (PAH).

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Study subjects are pretreated with a 5-day course of 3 mg dexamethasone qd directly before scanning. The scanning procedure itself will take approximately 1.5 hours. Before arriving at the department, patients should have fasted for 4 hours. In the first part of the investigation, patients will receive an intravenously injection with 400 MBq 11C-metomidate. In the second part of the investigation, 20 minutes after tracer injection, patients will be placed for approximately 45 minutes in the PET/CT camera to acquire whole-body images (head to pelvis).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age =/> 18 years;

2. Primary aldosteronism (PA) with successfully performed adrenal venous sampling (AVS).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Use of ketoconazole, metyrapone or cytostatic drugs during previous 6 months;

2. Pregnancy;

3. Severe contrast allergy;

4. Diabetes mellitus (type 1 or type 2);

5. Serious comorbidities precluding surgery.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	21-06-2010
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-01-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35185
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3629
NTR-old	NTR3817
CCMO	NL28866.042.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35185

Resultaten

Samenvatting resultaten
N/A